UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

HAEMONETICS CORP.,	:	
Plaintiff,	:	
v.	:	Civil Action Nos. 05-12572-NMG
FENWAL, INC.,	:	09-12107-NMG
Defendant.	:	

FENWAL, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Following the Federal Circuit's June 2, 2010 decision, and this Court's most recent Order, it is clear that no issues of material fact preclude summary judgment in this long-running dispute. The Federal Circuit has held as a matter of law that the term "centrifugal unit," as used each time in claim 16 of United States Patent No. 6,705,983 (the "'983 patent"), consistently means "a vessel and a plurality of tubes." *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010); SOF ¶ 21.[1] This Court has held that the parties are bound by their stipulation and prior understanding that "plurality of tubes" refers to the question-mark-shaped umbilicus in Fenwal's accused products and thus, forcefully rejected Haemonetics' attempt to argue otherwise. SOF ¶ 34. Thus, no trier of fact could find that Fenwal's ALYX® Component Collection System (the "ALYX System") centrifugal units infringe the '983 patent, making summary judgment appropriate.

As the Court is aware, the dispositive issue in these cases is claim 16's requirements that "the centrifugal unit hav[e] a radius between 25 and 50 mm and a height between 75% and 125% of the radius." SOF ¶ 9. A straightforward and indisputable measurement of the dimensions of the ALYX System centrifugal units demonstrates that neither the original accused ALYX System RBC centrifugal unit, nor the redesigned ALYX System RBC and RBC Plasma centrifugal units, meets these claim limitations. Accordingly, Fenwal moves for summary judgment of noninfringement. Fenwal also moves for summary judgment that claim 16 is invalid for indefiniteness.

[1] References to "SOF" are to Fenwal, Inc.'s Local Rule 56.1 Statement in Support of its Motion for Summary Judgment, filed herewith.

BACKGROUND

1. On December 22, 2005, Haemonetics sued Baxter Healthcare Corp.,[2] asserting that Baxter's ALYX System infringed the '983 patent (the "2005 action"). SOF ¶ 11. At trial, Haemonetics only asserted infringement of independent claim 16 and its dependent claim 17 and did not assert infringement under the doctrine of equivalents with respect to any claim terms. SOF ¶ 14. Haemonetics then withdrew claim 17 from the case before the case went to the jury, leaving only claim 16. *Id.*

2. Claim 16 of the '983 patent reads:

> 16. A ***centrifugal unit comprising a centrifugal component and a plurality of tubes***, said unit to turn around an axis to separate the components of a liquid, blood in particular, with such plurality of tubes displaying a single tubular component wherein said unit includes:
>
> a base in the form of a disk;
>
> an external cylindrical wall extending from the base;
>
> an internal cylindrical wall extending from the base and separated by the external wall so as to define a ring-shaped separation chamber among each other;
>
> a tubular housing almost extending coaxially to said rotating axis from the base to receive an end of a tubular unit; and
>
> a plurality of channels extending radially in the base of the centrifugal unit, with each channel providing communication between a respective tube of the tubular unit and the separation chamber, ***with the centrifugal unit having a radius between 25 and 50 mm and a height between 75 and 125% of the radius***.[3]

3. Based on a claim construction that focused on the measurement of the molded plastic centrifugal component only, and excluded the plurality of tubes found in the umbilicus of the accused Fenwal products, the jury found that claim 16 of the '983 patent was not invalid and

[2] Initially, Haemonetics brought suit against Baxter Healthcare Corp. and Baxter International, Inc. (collectively, "Baxter"). Fenwal was added as a defendant in March 2007 after Baxter divested its transfusion therapies business to Fenwal. SOF ¶ 11.

[3] Emphasis is added throughout unless otherwise indicated.

was infringed by Fenwal's ALYX System RBC centrifugal unit. SOF ¶ 15. The Court entered a permanent injunction and provisional royalty. *Id.* In light of the injunction, Fenwal redesigned both the RBC centrifugal unit and the RBC Plasma centrifugal unit so that the molded plastic centrifugal component by itself had a height that fell outside claim 16's requirements. SOF ¶ 17.

4. Fenwal appealed this Court's amended judgment, including the permanent injunction and the provisional royalty order. SOF ¶ 16.

5. On December 7, 2009, Fenwal announced that it would begin shipping ALYX System disposable kits that included a redesigned centrifugal unit. SOF ¶ 18. In response, on December 14, 2009, Haemonetics filed a second infringement action against Fenwal alleging that the "modified kits" also infringed the '983 patent (the "2009 action"). *Id.*

6. On appeal, the Federal Circuit reversed this Court's claim construction of the term "centrifugal unit" and held that, as used each time in claim 16 of the '983 patent, "centrifugal unit" means "a vessel and a plurality of tubes"; thus, the dimensions of the "centrifugal unit" set forth in the final limitations of claim 16 had to include both the molded plastic vessel *and* the "plurality of tubes." *Haemonetics Corp.*, 607 F.3d at 783; SOF ¶ 21. On appeal, Haemonetics had urged the Federal Circuit that including the tubing in the dimensional limitations of the "centrifugal unit" "would yield an absurdity," but the Federal Circuit responded: "Maybe so, but we do not redraft claims to contradict their plain language in order to avoid a nonsensical result." *Id.* at 782; SOF ¶ 24. The Federal Circuit also rejected Haemonetics' claim that the patent contained a correctable drafting error: "An error may have occurred in drafting claim 16, as Haemonetics' counsel indicated during the district court's claim construction hearing . . . but it is what the patentee claimed and what the public is entitled to rely on." *Id.* at 782-83; SOF ¶ 24. Accordingly, the Federal Circuit "vacate[d] the verdict and the award of prospective remedies and remand[ed] for proceedings" instructing this Court to determine infringement and validity of

claim 16 under the proper claim construction that "centrifugal unit" means the vessel *and* the "plurality of tubes." *See id.* at 783-84; SOF ¶ 22.

7. The Federal Circuit's opinion repeatedly acknowledged the vessel and the "plurality of tubes" as separate components, and consistently recognized the "plurality of tubes" as the question-mark-shaped tubing. For example, the Federal Circuit stated: "The '983 patent describes a centrifugal device comprising (1) a vessel in which blood components are separated in a separation chamber and (2) tubing through which blood flows in and out of the vessel. The tubing connects the spinning vessel to a non-rotating support structure, forming ***a question mark-shaped loop around the vessel***." *Id.* at 778; SOF ¶ 25. The Federal Circuit explained the principal patent drawing in consistent fashion: "Figure 1 shows the configuration of the ***vessel, marked as number 2, and its associated tubing, numbers 4a, 5a, and 6a, which are enclosed in tubular component 9***." *Id.* at 779; SOF ¶ 26. Moreover, in rejecting Haemonetics' argument that claim 16's preamble "merely states the claimed invention's field of use," the Federal Circuit stated that the preamble "unambiguously defines 'centrifugal unit' as 'comprising' ***two structural components***: a centrifugal component and a plurality of tubes." *Id.* at 781; SOF ¶ 27. Finally, in responding to the parties' indefiniteness arguments, the Federal Circuit stated: "[T]his court lacks any evidence in the record or any argument by the parties directed to where the height or radius are to be measured when the ***centrifugal unit includes not only the circular vessel but also the off-set, question mark-shaped tubes.***" *Id.* at 784; SOF ¶ 28.

8. On August 13, 2010, the Federal Circuit denied Haemonetics' petition for rehearing and rehearing en banc and issued its judgment as a mandate on August 20, 2010. SOF ¶ 31.

9. On September 9, 2010, in accordance with the Court's Order from the July 13, 2010 status conference (SOF ¶ 30), Haemonetics submitted new infringement contentions that the ALYX System centrifugal units infringe claim 16 of the '983 patent either literally or under

the doctrine of equivalents. Haemonetics also alleged that the "plurality of tubes" are no longer contained in the umbilicus, but are instead, "the tubes beginning at the base 150, extending through hub 120, and ending with the nipples 180," as identified in Figure 22 of U.S. Patent No. 6,284,142 (the "'142 patent"). SOF ¶ 32.[4] In other words, Haemonetics unilaterally determined that it would now choose to measure the "plurality of tubes" at its own selected point within the integral plastic vessel, and exclude rather than include the umbilicus in its measurements of radius and height, notwithstanding Haemonetics' earlier stipulated position[5] and the Federal Circuit's express holding. Haemonetics' new infringement contentions seek to retain the exterior measurements of the molded plastic vessel as the limits of the "centrifugal unit" for purposes of the critical claim 16 dimensions, despite the parties'—and the Federal Circuit's—shared understanding that the umbilicus constituted the "plurality of tubes."

10. In its October 13, 2010 Order, this Court enforced the Federal Circuit's mandate and held Haemonetics to its own stipulated position. When Haemonetics filed a motion for a status conference (2009 D.I. 60),[6] seeking further claim-construction proceedings, Fenwal opposed, and this Court denied the motion. SOF ¶¶ 33, 34. The Court stated that the parties have long had "a stipulated and shared understanding of the construction of 'plurality of tubes,'" as "two or more conduits that transport liquid materials (e.g. blood and blood components) into and out of the vessel." SOF ¶ 34. The Court rejected Haemonetics' contrary argument as "pure

[4] Nowhere within its new infringement contentions does Haemonetics actually articulate a doctrine of equivalents analysis for any of the claim terms in claim 16.

[5] In its opening *Markman* claim construction brief, Haemonetics stated that the "parties have been able to agree on the literal constructions of most of the claim terms or phrases for which claim construction may be necessary or appropriate." SOF¶ 12. Haemonetics included the agreed upon terms and phrases in Exhibit C to its memorandum titled "Table A – Stipulated Constructions for the '983 Patent." *Id.* Thus, as set forth in Table A, "plurality" was defined by the parties to mean "[t]wo or more" and "tubes" was defined by the parties to mean "[c]onduits that transport liquid materials (*e.g.*, blood and blood components) ***into and out of the vessel***." *Id.*; SOF ¶ 12.

[6] References to "2005 D.I." are to docket entries in Civil Action No. 05-12572-NMG and references to "2009 D.I." are to docket entries in Civil Action No. 09-12107-NMG.

sophistry," noting that, "[t]hroughout this protracted litigation, both parties consistently identified the 'plurality of tubes' as the umbilicus." *Id.* The Court refused to "revisit" the issue of what "plurality of tubes" meant in the patent or corresponded to in the accused Fenwal devices and invited dispositive motions, "if any," and oppositions, "if at all." *Id.*

11. Depicted below in Figures 1-3 are the original ALYX System RBC centrifugal unit (Figure 1), the redesigned ALYX System RBC centrifugal unit (Figure 2), and the redesigned ALYX System RBC Plasma centrifugal unit (Figure 3). As discussed below in Section II(B) and as identified in Figures 1-3, all three ALYX System centrifugal units have a radius of approximately 70 mm and a height of approximately 150 mm, resulting in a height-to-radius ratio of approximately 214%. SOF ¶¶ 35-37.

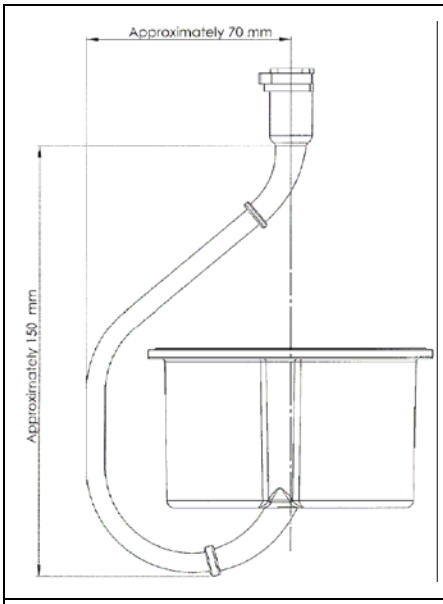


Figure 1

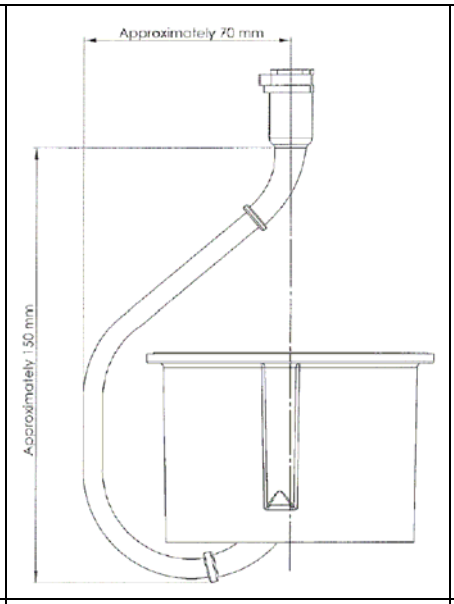


Figure 2

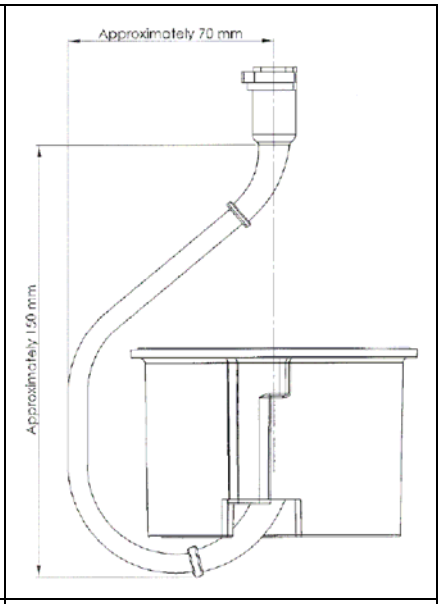


Figure 3

ARGUMENT

Claim 16 of the '983 patent requires that the "centrifugal unit," which the Federal Circuit held includes both the "vessel" and the "plurality of tubes," have "a radius between 25 and 50 mm and a height between 75 and 125% of the radius." As detailed above, the ALYX System centrifugal units each have a radius of approximately 70 mm and a height of approximately 150 mm (when the long, question-mark-shaped umbilicus is included as part of the "centrifugal unit"), yielding the conclusion that the heights of these units are approximately 214% of their radii.[7] Because the radii of the ALYX System centrifugal units are not "between 25 and 50 mm," and their heights are not "between 75 and 125% of the radius," they cannot literally infringe claim 16 of the '983 patent.

Nor can the ALYX System centrifugal units infringe under the doctrine of equivalents. The "radius between 25 and 50 mm" limitation was amended by the patent applicant during prosecution to include the lower limit of 25 mm and to place an absolute upper limit of 50 mm, and the "height between 75 and 125% of the radius" limitation—in particular, the 125% ceiling—was added by the applicant during prosecution. Both limitations were amended to narrow the claims so that the examiner would allow them. Under controlling precedent, these narrowing amendments foreclose Haemonetics from recourse to the doctrine of equivalents.

Given these undisputed facts and controlling law, the ALYX System centrifugal units cannot infringe claim 16 of the '983 patent, either literally or by equivalents.

[7] Fenwal has selected a conservative method of measuring the radii and heights of the ALYX System centrifugal units, in accordance with the argument set forth in Haemonetics' Federal Circuit appeal brief regarding how the centrifugal units should be measured when the umbilicus is included as part of the "centrifugal unit." *See* Section II(B) below. However, there are numerous other ways to measure the centrifugal units, examples of which include measuring the units while rotating, or measuring the units with the umbilicus in an extended state such that the entire length of the umbilicus coincides with the axis of rotation of the centrifugal units.

I. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). This standard applies equally to patent cases. *See Johnston v. IVAC Corp.*, 885 F.2d 1574, 1576-77 (Fed. Cir. 1989). Summary judgment of noninfringement is appropriate where "no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee." *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1353 (Fed. Cir. 2001).

II. AS A MATTER OF LAW, THE ALYX SYSTEM CENTRIFUGAL UNITS DO NOT INFRINGE CLAIM 16 OF THE '983 PATENT, EITHER LITERALLY OR UNDER THE DOCTRINE OF EQUIVALENTS

Determining patent infringement is a two-step process requiring, first, "determining the meaning and scope of the patent claims asserted to be infringed" and, second, "comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

A. "Centrifugal Unit" As Used In The Body Of Claim 16 Means The "Vessel" And The "Plurality Of Tubes" Together

The Federal Circuit held that the term "centrifugal unit" in claim 16 means "a vessel ***and*** a plurality of tubes." 607 F.3d at 783; SOF ¶ 21. Thus, the radius and height requirements of claim 16 apply to the combined "vessel" and "plurality of tubes."

In its opinion, the Federal Circuit repeatedly acknowledged that the "vessel" and the "plurality of tubes" were separate components, and consistently recognized the "plurality of tubes" as the question-mark-shaped tubing around the vessel:

- In describing the '983 patent, the Federal Circuit stated: "The '983 patent describes a centrifugal device comprising (1) a vessel in which blood components are separated in a separation chamber and (2) tubing through which blood flows in and out of the vessel. The tubing connects the spinning vessel to a non-rotating support structure, forming ***a question mark-shaped loop around the vessel***." 607 F.3d at 778. The Federal Circuit also stated: "Figure 1 shows the configuration

of the ***vessel, marked as number 2, and its associated tubing, numbers 4a, 5a, and 6a, which are enclosed in tubular component 9***." *Id.* at 778-79; SOF ¶¶ 25, 26.

- In rejecting Haemonetics' argument that claim 16's preamble "merely states the claimed invention's field of use," the Federal Circuit stated that the preamble "unambiguously defines 'centrifugal unit' as 'comprising' ***two structural components***: a centrifugal component and a plurality of tubes." *Id.* at 781; SOF ¶ 27.

- In responding to the parties' indefiniteness arguments, the Federal Circuit stated: "[T]his court lacks any evidence in the record or any argument by the parties directed to where the height or radius are to be measured when the ***centrifugal unit includes not only the circular vessel but also the off-set, question mark-shaped tubes.***" *Id.* at 784; SOF ¶ 28.

Notwithstanding the Federal Circuit's clear acknowledgement of the "plurality of tubes" as the umbilicus, Haemonetics attempted to assert (in its new infringement contentions) that the claimed "plurality of tubes" in the ALYX System begin at the base 150, extend though hub 120, and end at the nipples 180 as identified in the figures of the '142 patent—entirely omitting the umbilicus. SOF ¶ 32. However, consistent with the Federal Circuit's opinion, this Court has already ruled that Haemonetics is precluded from making that or any other new assertion for the "plurality of tubes," holding that "[t]hroughout this protracted litigation, ***both*** parties consistently identified the 'plurality of tubes' as the umbilicus," and further that "the doctrine of judicial estoppel prevents Haemonetics from now asserting a different construction of 'plurality of tubes.'" SOF ¶ 34.

Accordingly, it is the law of the case that the claimed "centrifugal unit" is the vessel, and its associated tubing—the "plurality of tubes"—is the long, question-mark-shaped umbilicus. Claim 16's required dimensions thus apply to this combination of structures.

B. The "Centrifugal Units" Of The ALYX System Do Not Literally Infringe Because They Have Dimensions Well Outside The Scope Of Claim 16's Requirements

The 2005 action involves the original ALYX System RBC centrifugal unit, while the 2009 action involves the redesigned ALYX System RBC and RBC Plasma centrifugal units.

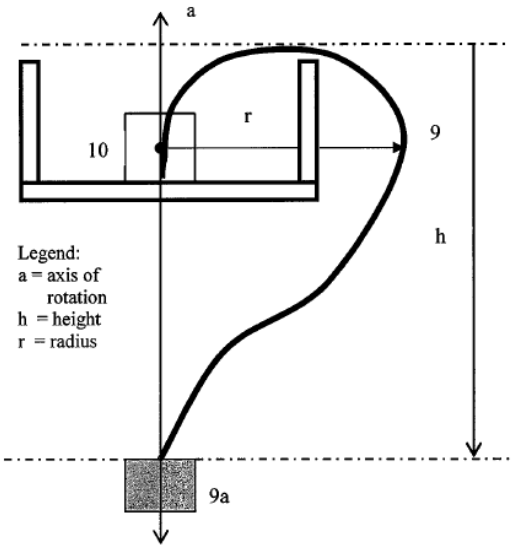
With respect to all three devices, when measuring the dimensions for claim 16 purposes, the measurements of the height and radius of these "centrifugal units" includes the vessel and the long, question-mark-shaped umbilicus. The dimensions of the original and redesigned ALYX System centrifugal units fall outside the scope of claim 16.

In its Federal Circuit appeal brief, Haemonetics itself suggested how these measurements should be made:

> Applying Fenwal's construction [*i.e.*, the construction ultimately adopted by the Federal Circuit], the radius of a device covered by Claim 16 would run from the center of the vessel, through the wall of the vessel, through whatever air space [that] may exist as a gap between the vessel and the tubing, and to the tubing itself (*see* A197).
>
> Fenwal's measurements for height and radius would, therefore, include the tubing and gap . . . .[8]

SOF ¶ 23.

[8] Haemonetics' citation to "A197" referred to page 16 of Baxter's Opening Markman Brief (2005 D.I. 30). SOF ¶ 23. That page includes the below figure, which is a simplified version of Figure 1 from the '983 patent. Thus, Haemonetics' argument relating to the radius including the gap between the vessel and the tubing refers to the radius of the vessel 10 and tubing 9, identified by arrow "r" in the figure. *See also Haemonetics Corp.*, 607 F.3d at 788-89 ("The '983 patent describes a centrifugal device comprising (1) a vessel in which blood components are separated in a separation chamber and (2) tubing through which blood flows in and out of the vessel. The tubing connects the spinning vessel to a non-rotating support structure, forming a question mark-shaped loop around the vessel . . . . Figure 1 shows the configuration of the vessel, marked as number 2, and its associated tubing, numbers 4a, 5a, 6a, which are enclosed in tubular component 9." Thus, the Federal Circuit agrees that when measuring the dimensions of the "centrifugal unit" in accordance with its revised claim construction, the gaps between the vessel and the umbilicus are included.



Thus, as depicted in Figures 1, 2 and 3 above, the original ALYX System RBC centrifugal unit, as well as the redesigned ALYX System RBC and RBC Plasma centrifugal units, each have a radius of approximately 70 mm and a height of approximately 150 mm, resulting in each unit having height-to-radius ratios of approximately 214%. These units cannot infringe claim 16, because their radii exceed the claim limit of 50 mm and their height-to-radius ratios exceed the claim's 125% ceiling.

C. The ALYX System Centrifugal Units Do Not Infringe Claim 16 Under the Doctrine of Equivalents

A device that does not literally infringe a patent may, under certain circumstances, still infringe under the doctrine of equivalents. *See Warner-Jenkinson*, 520 U.S. at 21; *Cabot Safety Intermediate Corp. v. Howard S. Leight & Assocs.*, 992 F. Supp. 463, 466 (D. Mass. 1998) (Gorton, J.). However, there is a significant threshold legal limitation on the application of that doctrine—that of prosecution history estoppel. A patentee may not claim equivalence of a claim limitation if that limitation was amended during prosecution of the patent to narrow the claims so as to achieve allowance. Prosecution history estoppel thus "prevents recapture of subject matter surrendered during prosecution of the patent." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995). Statements, claim amendments, and arguments made during prosecution of a patent application can estop the patentee from using the doctrine of equivalents to try to recover the ground that was surrendered during prosecution in order to get the claims allowed. *See Cabot Safety*, 992 F. Supp. at 466 (prosecution history estoppel "bars a patentee from construing its claims in a way that would resurrect subject matter previously excluded by claim limitations added in order to avoid prior art"); *accord Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1579 (Fed. Cir. 1983) (prosecution history estoppel "limits a patentee's reliance on the doctrine of equivalents by preventing him from contending later in an

infringement action that his claims should be interpreted as if limitations added by amendment were not present").

Prosecution history estoppel "is not limited to the applicant's own words, but may embrace as well the applicant's responses to the examiner's actions. If the patentee does not rebut an examiner's comment or acquiesces to an examiner's request, the patentee's unambiguous acts or omissions can create an estoppel." *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1357 (Fed. Cir. 2004).

In particular, "a narrowing amendment made to satisfy *any* requirement of the Patent Act may give rise to an estoppel" regardless of "whether the amendment was made to avoid the prior art or to comply with § 112." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736-37 (2002); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007).

1. Prosecution History Estoppel Bars Haemonetics From Asserting Infringement By Equivalents

The prosecution history of the '983 patent is crystal clear: Haemonetics added the radius (25-50 mm) and height (125% of the radius) limits in order to achieve allowance of claim 16. Accordingly, Haemonetics cannot claim any range of equivalents for those limitations, and certainly cannot capture Fenwal's accused devices, which are substantially beyond those claimed limits.[9]

[9] While prosecution history estoppel is dispositive of this motion and in view of the fact that Haemonetics failed to set forth any doctrine of equivalents analysis in its September 9, 2010 infringement contentions, it is also clear that the ALYX System centrifugal units do not satisfy the function-way-result test for equivalence, *see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1949), nor do they satisfy the alternative, "insubstantial difference" test for equivalence, *see id.* at 610, because the radius and height of the ALYX System's centrifugal units are substantially in excess of those required by claim 16.

a. The Radius And Height Of Claim 16 Were Amended To Overcome The Examiner's Rejection

The original '983 patent application was filed with 21 claims. SOF ¶ 2. In a Preliminary Amendment dated October 5, 2001, Rochat (the named inventor) canceled as-filed claims 1-21 and added new claims 22-42. SOF ¶ 3. In its originally-filed, pre-amended form, new claim 36, which became issued claim 16, read as follows:

> 36. A centrifugal unit comprising a centrifugal component and a plurality of tubes, said unit to turn around an axis to separate the components of a liquid, blood in particular, with such plurality of tubes displaying a single tubular component wherein said unit includes:
>
> a base in the form of a disk;
>
> an external cylindrical wall extending from the base;
>
> an internal cylindrical wall extending from the base and separated by the external wall so as to define a ring-shaped separation chamber among each other;
>
> a tubular housing almost extending coaxially to said rotating axis from the base to receive an end of a tubular unit; and
>
> a plurality of channels extending radially in the base of the centrifugal unit, with each channel providing communication between a respective tube of tubular unit and the separation chamber, ***with the centrifugal unit having a radius that is smaller than approximately 50 mm and a height that is approximately 75% greater than the radius.***

Id.

During prosecution of the Rochat application, in an Office Action mailed on April 3, 2003, the examiner rejected new claim 36 under 35 U.S.C. § 112, ¶ 1, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."[10] SOF ¶ 4. In support of the rejection, the examiner stated:

[10] The examiner also rejected new claim 36 under 35 U.S.C. § 112, ¶ 2, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention" and requested, among other things, that the Applicant clarify the wording in claim 36 by inserting "the" before tubular. SOF ¶ 4.

"The specification does not support the radius and height ranges set forth in claim 36 . . . The only radius and height ranges which are considered supported appear in claim 1 as originally filed (now canceled) which are equivalent to the ranges recited in new claim 22."[11] *Id.* In other words, "[t]he only radius and height ranges" that the examiner believed could have been claimed in the '983 patent were the "radius between 25 and 50 mm and a height between 75 and 125% of the radius."

The examiner indicated that new claim 36 "would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, first and second paragraphs." SOF ¶ 5. Moreover, the examiner stated that new claim 22 was allowable over the prior art and in support of the allowability of claim 22 stated,

> [t]he prior art of record does not teach or fairly suggest the recited blood centrifuge having a centrifugal unit with the claimed radius and height. ***Applicant has established the criticality of and therefore the nonobviousness of the radius and height parameters*** throughout the specification (including but not limited to size and weight reduction, ease of transport and handling, disposability and economical cost, and enabling the re-injection of the donor's erythrocytes).

Id. Thus, the "radius and height parameters" in claim 22—25-50 mm and 75%-125% of the radius, respectively—were found by the examiner to be "critica[l]" to patentability.

In response to the Section 112, ¶¶ 1 & 2 rejections, in an amendment dated September 11, 2003 ("Response A"), Rochat amended originally-filed claim 36 to recite:

> a plurality of channels extending radially in the base of the centrifugal unit, with each channel providing communication between a respective tube of <u>the</u> tubular unit and the separation chamber, with the centrifugal unit having a radius <u>between 25 and 50 mm and a height between 75 and 125% of the radius</u> ~~that is smaller than approximately 50 mm and a height that is approximately 75% greater than the radius~~.[12]

[11] New claim 22 recited "wherein the centrifugal unit has a radius between 25 and 50 mm and a height between 75 and 125% of the radius." SOF ¶ 3.

[12] Underlining indicates added subject matter and strikethroughs indicate deleted subject matter.

SOF ¶ 6. In short, Rochat had to add the same "critica[l]" radius and height limitations contained in application claim 22, because the examiner viewed those limitations as "[t]he only radius and height ranges which are considered supported" by the patent specification.

In responding, Rochat did not rebut the examiner's rejections, but instead stated that new claim 36 has "been amended to require 'a radius between 25 and 50 mm and a height between 75 and 125% of the radius.'" SOF ¶ 7. Nor did Rochat respond to or in any way refute the examiner's statement that the "critica[l]" 50 mm radius and 125% height limitations were "[t]he only [ones] considered supported" by the specification. *Id.*

b. The Amendments To Claim 16 Were Narrowing Amendments Made To Satisfy A Requirement Of The Patent Act

Prior to amending the claims in Response A, new claim 36 (which became issued claim 16) claimed a centrifugal unit having "a radius that is *smaller than approximately* 50 mm and a height that is *approximately 75% greater* than the radius." SOF ¶ 3. New claim 36 was amended in Response A to claim a centrifugal unit having "a radius between 25 and 50 mm and a height between 75 and 125% of the radius," thereby narrowing the claimed radius range by 25 mm. SOF ¶ 6. Rochat also deleted the term "approximately" from the radius recitation, thereby placing a precise upper limit on the radius, and in so doing, also narrowed the claimed radius range. *Cf. Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1581 (Fed. Cir. 1995) ("The addition of 'approximately' which means 'reasonably close to,' *eliminates* the precise lower limit of that range, and, in so doing *extends* the scope of the range.") (footnote omitted); SOF ¶ 6.[13]

[13] In its opposition to Fenwal's withdrawn Motion for Summary Judgment of Noninfringement submitted in the 2009 case (D.I. No. 8), Haemonetics conceded that at least the radius limitation was narrowed during prosecution, though it contended that the height limitation was unaffected by estoppel. *See* SOF ¶ 20 ("A review of the file history clearly evinces that while the radius limitation may have been narrowed during prosecution of the '983 Patent, no such narrowing occurred with respect to the height limitation"); *Id.* ("And while Haemonetics *may* be estopped from asserting equivalents with respect to the radius limitation, no such estoppel is warranted with respect to the height limitation.") (emphasis in original). That latter contention was erroneous, of course, because the height limitation was itself added in response to the examiner's view that the 75%-125% range was the only one

Further, by the amendment in Response A, Rochat added to new claim 36 an upper limit of "125% of the radius" to the height of the unit, thereby limiting the claimed height to "between 75 and 125% of the radius." SOF ¶ 6. Rochat also deleted the term "approximately" from the height recitation, which, as with the radius limitation, placed a precise limit on and further narrowed the height of the unit. *Id.* As claimed, the height of the unit is directly dependent on the radius of the unit. Thus, because the claimed radius range was reduced, the claimed height range of the unit was also reduced.

As outlined above, new claim 36 was rejected under Section 112. In response to the examiner's rejections and comments that new claim 36 would be allowed if rewritten to overcome the Section 112 rejections, Rochat did not rebut the rejections, but instead simply acquiesced to the examiner's rejections by amending new claim 36 as the examiner had suggested. It is clear that the Rochat application would not have been allowed had these amendments not been made. Accordingly, as a matter of law, Rochat disavowed any claim to centrifugal units having radii greater than 50 mm, or heights greater than "125% of the radius." *See, e.g.*, *Cross Med. Prods.*, 480 F.3d at 1341 ("'[I]f a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply. A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112.'").

Accordingly, because the amendments to claim 16 were narrowing amendments made to satisfy a requirement of the Patent Act, Haemonetics is estopped from claiming any equivalents of the claimed radius and height of the centrifugal unit.

(continued…)

supported by the patent specification, and because the "125% of the radius" height limit is, by definition, tied to the dimension of the radius, which was itself narrowed by amendment.

2. Haemonetics Cannot Rebut The Presumption Of Prosecution History Estoppel Created By The Narrowing Amendments To New Claim 36

The Supreme Court has identified three limited instances in which a particular equivalent may not be surrendered by a narrowing amendment: (1) when the equivalent is "unforeseeable at the time of the application"; (2) when the rationale underlying the amendment bears "no more than a tangential relation to the equivalent in question"; or (3) if there is another "reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Festo*, 535 U.S. at 740-41. If the patentee fails to rebut the presumption of total surrender in one of these three manners, then prosecution history estoppel will bar the patentee from relying on the doctrine of equivalents. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367 (Fed. Cir. 2003).

None of those three limited exceptions applies here. *First*, it was clearly foreseeable at the time the patent was written that a centrifugal unit could have a radius that was above the claimed range of "between 25 and 50 mm" and a height that was above the claimed range of "between 75 and 125% of the radius." In fact, the '983 patent specifically discusses prior centrifugal devices having larger components, including centrifuge units with larger dimensions, which would include units with larger height-to-radius ratios. *See, e.g.*, Exhibit 1 to the SOF at col. 2, lines 33-36; col. 6, line 66 to col. 7, line 9; col. 8, lines 1-12; col. 8, lines 35-41. Haemonetics cannot claim unforeseeability.

Second, Haemonetics cannot rebut the presumption of surrender by asserting that the amendments bore "no more than a tangential relation to the equivalent in question." *Festo*, 535 U.S. at 740. As the Federal Circuit has explained, "the tangential relation criterion for overcoming the *Festo* presumption [of surrender] is very narrow." *Cross Med. Prods.*, 480 F.3d at 1342. The "'criterion asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.'" *Id.* (quoting *Festo*, 344 F.3d at 1369). Here,

the amendments to new claim 36 to limit the radius to "between 25 and 50 mm" and the height to "between 75 and 125% of the radius" were not tangential, but viewed by the examiner as "critica[l]"—they were in direct response to the examiner's rejection of these claims under Section 112 because of lack of support in the specification for the originally-claimed radius and height limitations. Haemonetics cannot possibly claim that the amendment was tangential, either.

Finally, Haemonetics cannot rebut the presumption of surrender because Rochat could have drafted the claims to cover a centrifugal unit having a radius greater than 50 mm and a height-to-radius ratio greater than 125%. If Rochat had wanted to claim broader radius and height ranges for the centrifugal unit, he could have tried to challenge the examiner's rejections by appealing through the processes available in the Patent Office. *See Festo*, 535 U.S. at 734. Instead, he chose to acquiesce in the examiner's claim rejection, amend the claims to avoid that rejection, and specifically set the 50 mm radius limit and the 125% height-to-radius limit. Haemonetics is bound by law to those limits, and cannot assert equivalence with respect to them.

III. CLAIM 16 IS INVALID FOR INDEFINITENESS

Under Section 112, ¶ 2, a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." The Federal Circuit has made clear that the purpose of the definiteness requirement is to "assure[] that claims in a patent are sufficiently precise to permit a potential competitor to determine whether or not he is infringing." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003). In determining whether a claim satisfies Section 112, ¶ 2, a court must ask whether "one skilled in the art would understand the bounds of the claim when read in light of the specification." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). "If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted," the claim is invalid for indefiniteness. *Id.*

Haemonetics' current arguments about the boundaries of the "centrifugal unit" demonstrate the indefiniteness, and thus invalidity, of claim 16. As noted above, Haemonetics now asserts that the "plurality of tubes"—which for more than five years it agreed was the long, question-mark-shaped umbilicus—only includes the passages that are integral to the molded plastic vessel, so that the critical height and radius measurements can stop at the "nipples" of those vessels (the nipples to which the flexible plastic tubing of the umbilicus is connected).

This new argument was, of course, driven not by new insights or consistency, but rather by Haemonetics' sudden and urgent need following the Federal Circuit's decision to find another infringement position in order to continue these actions. But claims must be construed by their plain terms; lawyerly sophistry employed for litigation needs is not enough. *Boss Indus., Inc. v. Yamaha Motor Corp USA*, 2007 U.S. Dist. LEXIS 98875, at *34 (D. Utah Sept. 7, 2007) ("In summary, Boss' interpretations of 'base section' appear to derive not from an objective reading of the intrinsic record, but rather from Boss' litigation needs in striving to show infringement.").

The Court was correct in its October 13 Order to hold Haemonetics to its prior stipulations and positions. However, were it allowed or adopted, Haemonetics' new infringement position would yield an indefinite claim because no competitor or skilled artisan could know, based on the claim language and intrinsic record, how to measure the critical height and radius. *See id.* at *35 ("For the many reasons provided above, Boss' proposed interpretations . . . do not serve the public notice function of patent claims, and are improper as a matter of law."). The ease with which Haemonetics was able to switch its position based solely on the vicissitudes of litigation—from "the umbilicus is the 'plurality of tubes'" to "the umbilicus is not the 'plurality of tubes'"—demonstrates the indefiniteness of the claim.

If the meaning of "plurality of tubes" can be so easily twisted, like the proverbial "nose of wax," *see, e.g.*, *White v. Dunbar*, 119 U.S. 47, 51-52 (1886),[14] then claim 16 is, indeed, indefinite.

CONCLUSION

For the reasons set forth above, this Court should grant Fenwal's motion for summary judgment and dismiss Haemonetics' complaint in both the 2005 and 2009 actions.

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Respectfully submitted,

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[14] In *White v. Dunbar*, the Supreme Court stated: "Some persons seem to suppose that a claim in a patent is like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim; but not for the purpose of changing it, and making it different from what it is. The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." 119 U.S. at 51-52.

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CERTIFICATE OF SERVICE

I certify that, on November 12, 2010, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

Dated: November 12, 2010 /s/ Timothy D. Johnston